

### **REMARKS**

Applicant appreciates the Examiner's thorough examination of the application and requests reexamination and reconsideration of the application in view of the preceding amendments and the following remarks.

Through the above amendments, Applicant has amended claims 1, 9, 10, 12, 14, 22, 23, and 25. No new matter has been added through the above claim amendments. Accordingly, claims 1-30 remain pending in the subject application.

As Applicant's remarks with respect to the Examiner's rejections are sufficient to overcome these rejections, Applicant's silence as to assertions by the Examiner in the Office Action or certain requirements that may be applicable to such rejections (e.g., whether a reference constitutes prior art, motivation to combine references, assertions as to dependent claims, etc.) is not a concession by Applicant that such assertions are accurate or such requirements have been met, and Applicants reserve the right to analyze and dispute such assertions/requirements in the future. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicant expressly does not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

### **Claim Rejections – 35 U.S.C. § 103**

Claims 1-10, 12, 14-23, 25, and 27-30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller et al. (U.S. Publication No. 2002/0082519) in view of Moore (U.S. Patent No. 2,866,457).

"To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

Independent claim 1 as amended is directed to a biopsy system comprising a vacuum assisted biopsy device, a first fluid source, a second fluid source, a fluid connector configured to provide the first and second fluid sources in communication with the biopsy device, the fluid connector comprising a body member having a first input port in fluid communication with the first

fluid source, a first check valve in fluid communication with the first input port, a second input port in fluid communication with the second fluid source, a second check valve in fluid communication with the second inlet port, and an outlet port in fluid communication with the vacuum assisted biopsy device, wherein the first check valve is selectively opened when a vacuum is created in the fluid connector.

The Examiner alleged that Miller discloses a biopsy system including a body member (as best seen in Figure 12), a vacuum assisted biopsy device (300), a first fluid source (400) in communication with a first input port, a second fluid source (paragraph 90; "anesthetic") in fluid communication with a second input port, and a fluid connector (around 402) configured to provide the first fluid source in communication with the biopsy device and including a first valve (402) inherently having a cracking pressure and which is selectively opened by a change in pressure within an outlet port (paragraphs 141-146). The Examiner admitted that Miller fails to disclose that the first valve is a check valve and that the fluid connector includes a second check valve for providing the second fluid source in communication with the biopsy device. The Examiner further alleged that Moore teaches a fluid connector comprising a first valve (9) comprising a check valve in communication with a first inlet port (around 10) and selectively opened by a change of pressure (Column 2, lines 22-44) within an outlet port (around 8), and a second check valve (22) for providing the second fluid source (26) in fluid communication with a fluid connector.

As noted above, independent claim 1 as amended includes that the first check valve is selectively opened when a vacuum is created in the fluid connector. Independent claim 14 also includes this feature.

Miller fails to disclose at least this feature of independent claim 1. The Examiner refers to paragraphs [0141] – [0146] of Miller to support the allegation that Miller discloses a first valve inherently having a cracking pressure and which is selectively opened by a change in pressure within an outlet port. However, this section of Miller discloses that the hydraulic control system 150 used to control the cutting feature of Miller can be modified to incorporate a fluid line that branches from pressure line 192. Pressure line 192 is pressurized when the reciprocating motor begins its return stroke, and "[p]ressure in the branch fluid line can be used to open the pinch valve 402, while a drop in pressure can operate to close the valve." Paragraph [0143] of Miller.

It is clear from this section of Miller that the pinch valve 402 is not selectively opened when a vacuum is created in the fluid connector as claimed by Applicant, but instead in response to a pressurized branch fluid line. Therefore, Miller fails to disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed in claim 1 of the subject application.

As noted above, independent claim 14 also includes the feature of the first check valve selectively opened when a vacuum is created in the fluid connector. Therefore, for at least the reason set forth above, Miller fails to disclose this feature of independent claim 14.

Further, Moore also fails to disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed by Applicant. Moore discloses check valves that permit free fluid flow in one direction. If fluid flow reversal occurs, the check valve closes to prevent the back-flow of fluid. See Col 2, lines 22-31 of Moore. Moore also discloses maintaining a check valve in a closed position as by application of pressure from spring 25, so that the check valve can only be moved out of the sealing position upon application of a positive external fluid force. See Col 2, lines 32-44 of Moore. However, nowhere does Moore disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed by Applicant.

Therefore, as none of the cited references disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed by Applicant, the combination of references fails to teach or suggest all of the elements of independent claims 1 and 14. Thus, the combination of references fails to render independent claims 1 and 14 obvious. Accordingly, independent claims 1 and 14, and dependent claims 2-13 and 15-30 are patentable over the references for at least this reason.

Moreover, it should be noted that dependent claims 2-13 and 15-30 each contain additional recitations that are separately patentable as well. For example, the cited references fail to disclose the vacuum created in the fluid connector by the vacuum assisted biopsy device configured to draw a predetermined amount of fluid from the second fluid source through the output port and into the biopsy device when the second fluid source is connected thereto as claimed in claims 12 and 25 of the subject application.

Claims 11, 13, 24 and 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Miller (U.S. Publication No. 2002/0082519) in view of Moore U.S. Patent No. 2,866,457) and further in view of Turturro et al. (U.S. Patent No. 6,331,165).

As noted above, Miller and Moore both fail to disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed in independent claims 1 and 14 of the subject application. The Examiner alleged that Turturro discloses a biopsy system comprising luer fittings for the purpose of providing quick and easy connection and disconnection. However, as with Miller and Moore, Turturro also fails to disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed by Applicant in independent claims 1 and 14.

Therefore, as none of the cited references disclose the first check valve selectively opened when a vacuum is created in the fluid connector as claimed in independent claims 1 and 14, the combination of references fails to teach or suggest all of the elements of independent claims 1 and 14, and thus fails to render the claims obvious. Accordingly, independent claims 1 and 14, and dependent claims 11, 13, 24 and 26 are patentable over the cited references for at least this reason.

### **Conclusion**

In view of the above amendments and remarks, it is respectfully submitted that the pending application is in condition for allowance. If, however, there are any outstanding issues that can be resolved by telephone conference, the Examiner is earnestly encouraged to telephone the undersigned representative.

It is believed that no fees are due with this response. However, if any fees are required in connection with the filing of this paper that are not identified in any accompanying transmittal, permission is given to charge our Deposit Account No. 18-0013, under Order No. 65937-0045 from which the undersigned is authorized to draw. To the extent necessary, a petition for extension of time under 37 C.F.R. §1.136 is hereby made, the fee for which should also be charged to this Deposit Account.

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Respectfully submitted,

Electronic signature: /Jason D. Shanske/

Jason D. Shanske

Registration No.: 43,915

Kristin L. Murphy

Registration No.: 41,212

RADER, FISHMAN & GRAUER PLLC

Correspondence Customer Number: 82078

Attorneys for Applicant

R0586869